NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GLAXOSMITHKLINE CONSUMER HEALTHCARE, L.P.,	:	Civ. No. 05-898 (DRD)
Plaintiff,	:	**O P I N I O N**
v.	:	
MERIX PHARMACEUTICAL CORP.,	:	
Defendant.	:	

Robert J. Del Tufo, Esq.
Kenneth A. Plevan, Esq.
SKADDEN, ARPS, SLATE,
MEAGHTER & FLOM, LLP
Four Times Square
New York, New York 10036-6522
Attorneys for Plaintiff GlaxoSmithKline
Consumer Healthcare, L.P.

James S. Richter, Esq.
WINSTON & STRAWN LLP
The Legal Center
One Riverfront Plaza, 7th Floor
Newark, New Jersey 07102
Attorneys for Defendant,
Merix Pharmaceutical Corp.

Of Counsel:

Kimball R. Anderson, Esq.
Stephen P. Durchslag, Esq.
Ronald Y. Rothstein, Esq.
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, IL 60601

Debevoise, Senior District Judge

Plaintiff, GlaxoSmithKline Consumer Healthcare, L.P. ("Glaxo") commenced this action against defendant, Merix Pharmaceutical Corporation ("Merix"), asserting claims for false advertising under Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), and the New Jersey Consumer Fraud Act, N.J.S.A. §58:8-2. Glaxo moved for a preliminary injunction. After a three-months expedited discovery period the court held a five-day hearing during which it heard testimony, received deposition transcripts and received in evidence numerous exhibits. For the reasons that follow a preliminary injunction will issue. This opinion constitutes the court's findings of fact and conclusions of law.

I. The Parties and The Products

Glaxo is a Delaware limited partnership with its principal U.S. office in Pennsylvania. It is the over-the-counter division of GlaxoSmithKline, one of the largest pharmaceutical companies in the world headquartered in the United Kingdom with extensive operations in the United States. Among the many pharmaceutical products that Glaxo sells are ABREVA, a non-prescription cold sore remedy and VALTREX a prescription drug for cold sores and herpes.

Merix is an Illinois corporation with its principal place of business in that state. In 1999 Meryl Squires formed Merix. Its principal activity is the sale on the internet and at drug and convenience stores nationwide of RELEEV, a cold sore remedy. Merix employs four persons - Ms. Squires, two of her daughters and a clerical employee.

Glaxo's non-prescription cold sore product, ABREVA, is approved by the Food and Drug Administration to shorten the healing time for cold sores. ABREVA has been publicly available since the fall of 2000 following the FDA's July 25, 2000 approval of New Drug Application 20-

941 for over-the-counter sales. The product generally sells at retail for approximately $15-$18 per 2-gram tube.

Ms. Squires, a cold sore sufferer since 1987, pursued relief from its symptoms through the use of various products and ultimately discovered that benzalkonium chloride (a common topical antiseptic used for years in the United States) combined with Echinacea (a natural remedy) provided her with such relief. She asked friends to use her product and they reported enjoying relief. She obtained two United States patents on the product, one issuing on March 12, 2002 and one on April 19, 2002. She named this substance VIRACEA, registering the name as a trademark. RELEEV is now the product's name and is the name which will be used throughout this opinion.

In 1998 Ms. Squires communicated with Glaxo and offered to license her product to it. Glaxo declined the offer and in April, 1998 Ms. Squires began advertising and selling her product through a website. Merix first entered the retail drug store chains with RELEEV in June of 2003.

RELEEV is sold in a price range of $15 - $20 per tube to consumers nationwide through Merix's website and other buy-direct web sites. It is also available at national and regional drug retailers where RELEEV is often displayed adjacent to or in the same shelf area as ABREVA and other cold sore remedies.

II. Glaxo's Challenges to Merix's Advertising

From the outset Merix made extravagant claims for RELEEV on the internet, on its packaging and in its advertising and promotional material, claims that Glaxo concluded were materially false and misleading. The precise claims will be discussed at length below.

In early 2003 Glaxo alerted the FDA to what it considered to be Merix's unfounded claims concerning its RELEEV product. In May 2003 the FDA sent a warning letter to Ms. Squires, who, in response, modified some of her claims about RELEEV. When Merix entered the retail drug store chain market with RELEEV it commenced head-to-head competition with Glaxo's ABREVA. Glaxo thereafter monitored Merix's sales practices and the effect they were having on Glaxo's sales.

It is Glaxo's contention that Merix on its packages and in its advertising and promotional material made materially false claims regarding RELEEV's efficacy in treating cold sores, thus unfairly competing with Glaxo. The allegedly false claims include:

1. RELEEV has been "clinically proven": (a) to be a "1 Day Cold Sore Treatment" and (b) to "prevent outbreaks".

2. RELEEV is endorsed by the University of Chicago;

3. Clinical research by RELEEV's Principal Clinical Investigator has been published;

4. RELEEV uses the product name Vira Medx;

5. The RELEEV package bears "before and after" photographs purportedly showing marked improvement after 1 day, after 3 days and after 5 days.

On July 2, 2004 Glaxo filed an advertising challenge with the National Advertising Division of the Better Business Bureau (the "NAD"), challenging the truthfulness and accuracy of the RELEEV claims. In response Merix submitted several clinical studies which purportedly substantiated its claims for RELEEV. Glaxo asserted that the clinical studies suffer from serious shortcomings in methodology, data collection and analysis and fall far short of meeting U.S. drug testing standards.

On December 24, 2004 the NAD issued its decision finding in favor of Glaxo on all issues that Merix had contested. Thereupon Merix filed an appeal to the National Advertising Review Board on each ruling against it. Rather than proceeding further before the NAD Glaxo commenced this action on February 16, 2005.

III. The Merix Claims for RELEEV

On the first day of the preliminary injunction hearing Merix advanced the argument that injunctive relief should be denied on mootness grounds because it had revised its packaging and promotional material to remove the arguably false claims. Glaxo asserts that remaining claims continue to be false and misleading, and in any event the abandoned claims that Merix has been making about RELEEV since its introduction into the market cast light upon its remaining claims and are otherwise relevant to the question whether preliminary injunctive relief should be granted. At this stage of the proceeding Merix either concedes or makes little if any effort to defend the accuracy of the claims which it has removed from its packages and promotional material.

A. Prevention Claim: Merix claimed on its packaging when it introduced RELEEV in the drug trade in 2003 and on its new packaging introduced in March 2004 that RELEEV prevented cold sores. The "Directions" on the packages instructed: "To prevent outbreaks use one drop per day on area and surrounding area where outbreaks occur." Merix's January 2005 Sales Presentation advised that RELEEV "Prevents Outbreaks." A letter dated March 3, 2004 assured Walgreens that: "RELEEV deactivates the herpes virus. It heals cold sores in as little as one day and it can prevent outbreaks." Although this claim was typically placed in close proximity to a "clinically proven" claim, suggesting that it was clinically established, Ms. Squires admitted that

RELEEV had not been clinically proven to prevent cold sores and acknowledged that Merix did not have satisfactory support for the claim. It was a false establishment claim.

B. One-Day Healing Claim: Merix's packaging and promotional materials suggested that RELEEV healed cold sores in 24 hours. Prominently displayed on the front of the package introduced in March 2004 was the statement "1-Day Cold Sore Treatment." The prior package assured that "lesions resolved in 24 hours." The back panel of the revised packaging first shipped in the Spring of 2005 stated: "In clinical testing . . . lesions resolved in 24 hours." Promotional material provided the same assurances.

There is no clinical evidence to support these claims, and Ms. Squires testified at trial that she had decided to withdraw the 24-hour claim in late December 2004 or early 2005: "I decided I'm not going to make that claim until I can get clinical trials done, until we can substantiate it." The studies which Ms. Squires characterized as clinical reports, the reports of Dr. Betsy Singh and Professor Silvio Boraks, discredit the one-day healing claim and demonstrate its falsity.

C. Clinical-Testing Claim: Throughout the packaging and promotional material for RELEEV there appear frequent references to "clinically proven" by means of clinical and other scientific tests. The studies that Merix puts forth as clinical tests are i) three Brazilian studies by Professor Boraks, Department of Odontology, Cancer Institute, University of Sao Paulo, Brazil, ii) an "interim report" by Betsy Singh, Ph.D. of the Southern California University of Health Sciences and iii) a seven-year study conducted by Ms. Squires, which was reported on the RELEEV website.

Materials that Merix's sales representatives presented to retailers contained such representations as:

> "Clinically Proven"
>
> "Clinical Study . . . of more than 300 people proves RELEEV heals cold sores in 1 day.
>
> "Clinical Study . . . comparison, double blind testing against Zovirax and placebo showed RELEEV was 100% effective and much more effective against cold sores than Zovirax."

An October 2004 radio advertisement for RELEEV stated: "In clinical trials, [RELEEV] eased pain in minutes and sores were gone in minutes."

Glaxo's witnesses, Dr. Paul Shiffman, Dr. Pedro Garbes and Dr. Katie L. Dawson, testified about serious deficiencies in methodology, data collection and accuracy in the Boraks studies. Dr. Boraks did not testify, and Merix's expert, Dr. David Riley did not successfully rebut the testimony of Glaxo's expert witnesses.

The Singh study which, even as proposed, was only a pilot study, was cancelled by Merix before it was one-third completed with results from only 16 patients out of a planned 50. Ms. Squires testified that she directed Dr. Singh to halt the study prior to completion because "[t]here seemed to be some problem with the study."

The seven-year study upon which Merix relied was so defective that in responding to Glaxo's NAD challenge in August 2004, Merix did not attempt to defend it and instead agreed to delete it from its website.

In its proposed findings of fact submitted after the hearing Merix did not seek to justify use of the clinical studies as supporting Merix's more extravagant claims that RELEEV healed cold sores in one day or that sores were gone in about 24 hours. All Merix now claims for the various studies is that they establish that "RELEEV alleviated the symptoms of cold sores in less

than a day" (emphasis added) or that "RELEEV relieves the symptoms of cold sores in less than 24 hours." (emphasis added).

Akin to statements about clinical studies were Merix's references in their packaging and advertising to Dr. Kenneth Thompson, the University of Chicago and laboratory testing that Dr. Thompson conducted on RELEEV. Dr. Thompson of the University of Chicago had in fact tested RELEEV in a "basic science study" in a laboratory to test its effectiveness against certain herpes strains. He published his findings in the Journal of Antiviral Research to the effect that RELEEV was "shown to have good in-vitro activity against clinical strains of the herpes virus that causes cold sores." Although these laboratory tests do not, and cannot, establish drug efficacy in human beings, in its advertising Merix referred to them, to Dr. Thompson and to the University of Chicago to bolster its claims that RELEEV cured and prevented cold sores.

The March 2004 package had the following claim on the back panel:

> Publications of the testing conducted on Viracea (RELEEV) by Dr. Ken Thompson at the Clinical Microbiology Laboratory at The University of Chicago can be obtained from The Journal of Anti-viral Research or contact Merix Pharmaceutical Corp.

The new packaging introduced in the Spring of 2005 revised the language to read: "Published laboratory testing at the leading University in Chicago proves . . ." These references to Dr. Thompson and the University of Chicago which appeared prominently and frequently throughout Merix's packaging and advertising were clearly designed to lead the public to believe that the curative and preventive qualities which Merix claimed for RELEEV were supported by the eminent Dr. Thompson's laboratory experiments. These were false endorsements as neither Dr. Thompson nor the University of Chicago consented to the use of his/its name.

D. FDA - Approved/Registered Claims: In its advertising Merix claimed that RELEEV was registered, regulated or approved by the FDA as a cold sore drug, thus attempting to clothe its extravagant claims with the FDA's blessing. For example:

> FDA REGISTERED "Over the Counter" Treatment
>
> Regulated by the FDA as an OTC product, the formulation is comprised of Category I substances that meet the FDA Tentative Final Cold Sore Monograph for the status and the claims indicated. (emphasis in original)

There was conflicting testimony as to whether RELEEV's active ingredient, benzalkonium chloride comes within an FDA OTC Monograph for treatment of cold sores. Glaxo's Sue James testified that it does not. She noted that upon receipt of the report of the Panel studying fever blister and cold sore treatment drug products the FDA referred benzalkonium chloride to the Panel studying rule making concerning OTC first-aid antiseptic drug products for use on cuts and wounds and that, therefore, benzalkonium chloride was not available under an FDA Monograph for fever blisters and cold sores. Merix's Robert Pinco, a knowledgeable witness in the FDA regulatory field, testified that read together the various applicable Monographs, one of which approved benzalkonium chloride as an OTC first-aid antiseptic drug product, entitled Merix to market RELEEV as a cold sore treatment drug product pursuant to an FDA Monograph. No one questions the legality of Merix's sale of RELEEV as a cold sore remedy, and it will be assumed that the product comes within an FDA Monograph. That being said, however, neither Pinco's testimony nor the Monographs themselves support Merix's statements that RELEEV is "FDA REGISTERED," or that RELEEV is "Regulated by the FDA as an OTC product," or that because it is within an FDA monograph RELEEV "meet[s] . . . the claims indicated." Quite the contrary, as the Monographs themselves make clear.

The FDA has never approved RELEEV or its ingredients as a cold sore drug. Plaintiff's Exhibit 45 contains two OTC Monographs, each dated January 31, 1990: i) the proposed rule for Skin Protectant Drug Products for Over-the-Counter Human Use; Fever Blister and Cold Sore Treatment Drug Products, and ii) the proposed rule for External Analgesic Drug Products for Over-the-Counter Human Use; Proposed Rulemaking for Fever Blister and Cold Sore Treatment Products. In each Monograph the proposed definition of "fever blister, cold sore" is "A vesicle that occurs at the junction of the mucous membrane and skin on the lips or nose and is caused by the virus herpes simplex, type 1."

Both of these Monographs set forth the FDA approved claims that may be made with respect to the products covered by the respective Monogaphs:

> "Relieves dryness and softens colds sores and fever blisters," which may be followed by the optional statement "softens crusts (scabs) associated with cold sores and fever blisters." (Pl. Ex. 45, at 3369).
>
> "For the temporary relief of" (select one of the following: "Pain," "itching," or "pain and itching") (which may be followed by: "associated with" (select one or more of the following: "fever blisters," "cold sores," or "fever blisters and cold sores")). (Pl. Ex. 45, at 3383).

Merix's claim that RELEEV was registered with the FDA was false and in violation of an FDA regulation. 21 C.F.R. §207.39(2005). The limited claims which the Monographs approved demonstrate the falsity of Merix's assertion that the Cold Sore Monograph establishes that RELEEV meets the extravagant claims Merix made for it.

E. Miscellaneous Claims: Merix in its promotional material and advertising made a number of other claims for RELEEV which have no basis in fact.

An October 2004 radio advertisement on WOR-AM in New York contained the

following purported consumer testimonials:

> One man wrote to say that he is now in his 50's and has suffered from this curse since 17. Sores would last ten days. He bought RELEEV and applied it immediately. Pain eased in minutes and by the next day, the sores were almost entirely gone. He now won't leave home without it. And a woman wrote saying that she had tried everything, nothing worked. Then she tried RELEEV and it worked like it said it would. "Thank you, thank you," she says, "RELEEV gave me back my life."

This, in effect was a repetition of the insupportable false curative claims contained in the packaging and promotional material.

The use of the brand name "Vira Medx" conveys to consumers, falsely, that RELEEV is a medication that has been proven to cure cold sores by killing viruses. Merix achieves this effect by combining "Vir" from virus, "Med" from medication and "x" from Rx. The packaging that Merix proposed at the outset of the hearing changed the brand name to "VIMDX."

There appeared in Merix's April 2005 sales sheet the statement that RELEEV has been "[r]ated best and most effective by consumers." "Rated" suggests that the statement is based upon proper consumer research. Admitting that the only support for this claim was letters and calls it receives from consumers, Ms. Squires testified that she had withdrawn the statement.

Similarly, the assertion in its sales material of "99.8% Repeat Customer" is totally unsubstantiated as there was no evidence to support such a claim.

The assertion contained in versions of the Sales Presentation/Manual and Broker Manual that RELEEV "[s]tops the virus at the cell surface level" was also false as unsubstantiated. Ms. Squires testified that she has withdrawn the claim.

F. Totality of the Claims: The claims that Merix has made for RELEEV have thus been examined individually and have been found to be literally false or false in a variety of other ways.

When all the claims, whether verbal or pictorial are considered together the consumer cannot help but receive the impression that here is a wonder drug that can prevent cold sores and can cure them in a 24-hour period, as contrasted to the untreated cold sore's eight to nine day healing cycle- a claim that no other cold sore remedy can make. When analyzed, Merix's own evidence and admissions negate this overarching claim.

IV. Merix's Proposed Claims for RELEEV: Apparently recognizing the indefensible nature of its claims, on the eve of the June 14, 2005 hearing Merix abandoned many of them and proferred a new package design for RELEEV. Counsel stated in his opening argument that Merix had halted shipment of the prior versions of the packaging and that the new packaging was already being shipped. In fact the new packaging was not yet in use.

The front of the new package design stated:

> 1 Day Cold Sore Treatment
> Relieves Symptoms in Just a Day!

The top line is printed in bolder, larger type than the bottom line that is italicized and printed in smaller type.

In the upper right corner of the front panel the purchaser is advised to "See actual Before and After Photos on back panel."

The top of the back panel states that "Publications regarding this product can be obtained by contacting Merix Pharmaceutical Corp." Below this statement and to the right is the following: "Symptoms of cold sores relieved within 24 hours." To the left of this statement is the three side-by-side photographs purporting to show "Before" and "After" results from application of RELEEV at 1-, 3-, and 5 day stages of a cold sore. Each "After" photograph

shows healing of the cold sore lesions.

The only claim that Merix can truthfully make for RELEEV is that it provides relief from cold sore symptoms. There is no dispute that the symptoms of a cold sore are the subjective manifestations of pain, tingling and burning sensations. The symptoms are not the physical manifestations of the ulcer, blister and crust. Glaxo objects to the new packaging's representations that RELEEV "Relieves Symptoms in Just a Day" and "Symptoms of cold sores relieved within 24 hours." In fact Merix could legitimately represent that RELEEV relieves the symptoms, at least temporarily, shortly after application, long before the expiration of 24 hours. The reference to 24 hours is a rather obvious ploy to tie in the new packaging design to the old design which falsely promised a cure within 24 hours. However, if Merix wishes to make this lesser claim for the effect its product has upon cold sore symptoms there is no reason why it should not do so provided it is not used in association with other claims that suggest that RELEEV is a cure for the physical effects of cold sores. A relief of symptoms claims comes within a reasonable adaptation of the Monographs' permitted claims.

Other elements of the new packaging continue to suggest, falsely, that RELEEV is a cure for cold sores. The emphasis placed on "1 Day Cold Sore Treatment" is not cured by the statement under it printed in smaller italicized type: "Relieves Symptoms in Just a Day!"

The "Before" and "After" photographs, which accompanied the highly questionable Boraks studies, convey the unmistakable impression that RELEEV effects a cure of the physical manifestations of colds sores. As explained above, this is false.

The falsity of (i) the statement "1 Day Cold Sore Treatment" and (ii) the "Before" and "After" photographs is accentuated by the history of the packaging and promotional materials

that were in use since 2003. For two years sellers and purchasers of RELEEV have been exposed to the claims of 24-hour or 1 Day cures, the "Before" and "After" photographs evidencing such cures and all the false or misleading material purportedly evidencing such cures. Continued use "1 Day Cold Sore Treatment" and the "Before" and "After" photographs will necessarily lead former retailers and consumers to believe that the now abandoned claims are still viable, and thus encourage their continued purchasing of RELEEV. One cannot help but infer that this was the intent of continued use of these claims.

V. Discussion

In ruling on a motion for a preliminary injunction, the court must consider i) the likelihood that the moving party will prevail on the merits at the final hearing; iii) the extent to which the moving party is being irreparably harmed by the conduct complained of; ii) the extent to which the non-moving party will suffer irreparable harm if the preliminary injunction is issued; and iv) the public interest. Duraco Products, Inc. v. Joy Plastic Enterprises, Ltd., 40 F.3d 1431, 1438 (3d Cir. 1994).

A. Likelihood of Success: In its post-trial Proposed Findings of Fact and Conclusions of Law Merix makes no attempt to defend the claims of cure, prevention, validation by clinical studies, FDA registration and approval endorsement by Dr. Thompson and the University of Chicago and others discussed in Part III of this opinion. Unquestionably those claims violated Section 43(a) of the Lanham Act which provides:

> Any person who . . . uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin or his or her or another person's goods, services, or commercial activities,

> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. §1125(a).

These claims met all the criteria for a Lanham Act violation: i) Merix made false and misleading statements about its own product, ii) there was a tendency to deceive the retailers and consumers of RELEEV; iii) the deception was material in that it was likely to influence purchasing decisions, iv) RELEEV traveled in interstate commerce, and v) there was a likelihood of injury to Glaxo in terms of declining sales or loss of good will. Warner-Lambert Co. v. Breath Assure, Inc., 204 F.3d 87, 91-92 (3d Cir. 2000).

As noted above, certain of the claims were literally false, such as the claim that RELEEV prevents outbreaks of cold sores, that RELEEV resolved cold sores lesions in 24 hours and that this was established in clinical testing. Ms. Squires admitted that the clinical evidence did not support these claims and withdrew them. See Johnson & Johnson Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms., Inc. 19 F. 3d 125 (3d Cir. 1994); Castrol Inc., v. Quaker State Corp., 977 F. 2d 57 (2d Cir. 1992).

Where, as in the present case, a claim is completely unsubstantiated a plaintiff need not offer affirmative evidence in support of its contention that a challenged claim is false. Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co., 290 F. 3d 578, 590 (3d Cir. 2002); Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 228 n.7 (3d Cir. 1990).

The "Before" and "After" photographs contributed to the message Merix intended to convey, that RELEEV cured cold sores. Pictorial representations can convey false advertising

claims. Coca-Cola Co. v. Tropicana Prods., Inc., 690 F.2d 312, 317-18 (2d Cir. 1982); Gillette Co. v. Norelco Consumer Prods., Co., 946 F. Supp. 115, 128 (D. Mass. 1996).

Despite the fact that Merix has ceased using certain of its false claims and certain of the statements which implied the more explicit false claims, its most recent packaging and presumably its promotional material perpetuate the false claims of prevention and cure by use and emphasis of the phrase "1 Day Cold Sore Treatment" and by use of the "Before" and "After" photographs. The phrase 1 Day Cold Sore Treatment" is not neutralized by placing beneath it in much less prominent type the phrase "Relieves Symptoms in Just a Day!" There is nothing to modify the effect of the "Before" and "After" photographs.

Even without the prior history of deceptive packaging and advertising these two elements would convey the false impression that RELEEV effects a cure and prevents cold sores. In the context of two years usage of this phrase and the photographs, retailers and consumers who had been exposed to them would be more likely to interpret the language as suggesting that RELEEV cures and prevents cold sores.

Merix defends on the ground that it has ceased using the offending packaging and promotional material, and that when a defendant has ceased the allegedly offensive activity, no basis exists for an injunction. Oil Heal Institute v. Northwest Natural Gas, 708 F. Supp. 1118 (D. Or. 1988). In other words, Merix contends that the claim for injunctive relief has become moot. The short answer to this contention is that Merix has not ceased using elements of the offensive claims and that its new packaging continues to suggest falsely that RELEEV cures cold sores. It still has not limited its claims for RELEEV to alleviating symptoms of cold sores, which would come within the claims approved in the Monographs upon which it relies. It asserts in its post

trial Proposed Findings of Fact and Conclusions of Law that its claim is a "non-establishment claim" that RELEEV is a "one day treatment of cold sore symptoms" (at p 18). However, the language and photographs on the packaging as now written are not so limited. From June 2003 until the present Merix has modified its claims from time to time, but the claims are continually suggestive that RELEEV can do far more than relieve cold sore symptoms. Glaxo has established that it is likely to succeed on the merits of its federal Lanham Act cause of action, and by the same token it is likely to succeed on its New Jersey Consumer Fraud Act cause of action.

B. Irreparable Injury: Glaxo's Vice President Jeffrey Brown testified about the damage which Glaxo has suffered and, unless Merix is preliminarily enjoined, is likely to continue to suffer by reason of RELEEV's packaging and advertising claims. RELEEV competes directly with Glaxo's ABREVA, the only other brand selling in the price range of $15 - $20 per unit. Glaxo spends millions of dollars each year advertising ABREVA, the only OTC product approved by the FDA to shorten healing time.

RELEEV is marketed in the same area of stores as ABREVA and placed in proximity to it on the shelves. While ABREVA claims to shorten healing time it does not and cannot claim to cure cold sores in 24 hours or is a "1 Day Cold Sore Treatment" or prevents future cold sores. In the normal course of events a consumer will choose RELEEV over ABREVA by reason of RELEEV's purported superior curative properties.

The evidence demonstrates that Glaxo has suffered loss of sales. According to Mr. Brown ABREVA's sales have declined in stores carrying RELEEV as compared to increased sales of ABREVA during the same period of time in retail chains where RELEEV was not sold. He estimated that ABREVA's loss of market share to RELEEV in 2005 has been $2 million in

sales.

Merix notes the enormous sales of ABREVA and the over-all increase in its sales during the period RELEEV has been on the market. By October 2004 Glaxo's gross sales of ABREVA were more than $60 million. ABREVA had approximately 40% of the market share, while RELEEV had approximately 1.3%. By September 10, 2004, despite RELEEV's impact, ABREVA's over-all sales were up 10% from the prior year. This suggests that Glaxo's estimated $2 million loss of sales to Merix's RELEEV constituted a relatively slight degree of injury. Be that as it may, the injury was inflicted by the effect of false claims for RELEEV and, if Merix were allowed to continue making such claims, the degree of injury would likely increase in the future.

Failure of RELEEV to live up to its promises could reflect not only upon RELEEV and Merix, it could reflect adversely upon the reputation of Glaxo, the other seller of a high-priced cold sore remedy. Irreparable injury under the Lanham Act results from "loss of control of reputation, loss of trade, and loss of goodwill." Pappan Enterprises, Inc. v. Hardee's Food Sys., Inc., 143 F.3d 800, 805 (3d Cir. 1998). Glaxo has suffered these kinds of injuries in this case.

Noting that a plaintiff must demonstrate diligence to prevail on a motion for a preliminary injunction, Pharmacia Corp. v. Alcon Laboratories, 201 F. Supp. 2d 335, 383-84 (D.N.J. 2002), Merix argues that Glaxo's failure to timely bring this preliminary injunction application demonstrates that it is not suffering irreparable harm. Merix notes that Glaxo first learned of Merix's product seven years ago when Ms. Squires sought to determine if Glaxo would be interested in licensing her cold sore remedy. From 1998-2002 Ms. Squires sold her product over the internet, making many of the claims for it that the court has found to be false, all without

objection from Glaxo.

However, the critical date is the date when RELEEV entered into competition with ABREVA and when thereafter Glaxo concluded that RELEEV's false claims were causing it injury. Prior to that Glaxo would not have a viable cause of action against Merix.

Glaxo first learned that RELEEV was entering into direct competition with its ABREVA when in June 2003 a national retail chain began carrying RELEEV. Thereafter it began monitoring the effect RELEEV was having on the market for over-the-counter cold sore remedies and by April 2004 concluded that the competitive effect was real, having the consequences described above. Electing to pursue a voluntary false advertising claim before turning to litigation, Glaxo filed a challenge with the NAD on July 2, 2004. On December 12, 2004 the NAD issued its decision finding in favor of Glaxo on all contested issues. It was only after Merix filed an appeal on each ruling against it that on February 16, 2005 Glaxo filed this law suit.

This conduct, which entailed an initial resort to a consensual resolution of the controversy did not constitute unreasonable delay. Millenium Import Co. v. Sidney Frank Importing Co., 2004 WL 1447915 (D. Minn. June 11, 2004).

C. Injury to Merix: Merix contends that granting the injunctive relief Glaxo seeks would destroy the life work of Ms. Squires, a person who had worked her way through high school, attended community college at night, studying biology, all the while single-handedly raising three daughters. A cold sore sufferer herself, in about 1988 she discovered that benzalkonium chloride combined with Echinacea provided her with relief. She determine that the mixture also provided relief to friends, family members and colleagues.

Thereafter Ms. Squires obtained two patents for her creation and registered the name she gave to it, VIRACEA, with the United States Patent and Trademark Office. In April 1998 Ms. Squires began advertising and selling her product through a website (under its present name, RELEEV) and in June 2003, as noted above, introduced RELEEV into the retail drug store chain market. It undoubtedly required unusual efforts, salesmanship and creativity on the part of Ms. Squires and two of her daughters to develop packaging and promotional material for this new product and to enter so successfully into the market for cold sore remedies. None of these factors, however, can justify the sale and advertising of RELEEV by means of claims that are not true.

It is evident that Merix, through the efforts of its principal, has established itself in major United States drug chains and that RELEEV has become a popular cold sore remedy. Merix's gross profit on the sale of RELEEV is considerable. Its cost is $.80 per bottle. It is sold to retailers for $12 per bottle, with a recommended retail price of $15-$20 per tube - a price comparable to that of Glaxo's ABREVA. Merix's sales were $3.4 million in 2004. With estimated sales of 400,000 units in 2005, Merix's gross profits for that year could exceed $4 million. Merix has recently voluntarily withdrawn its principal representations suggesting curative and preventive qualities for RELEEV, apparently without fear that sales would be adversely affected. An injunction would ensure that these unfounded claims would not reappear in future packaging and promotional material and would prevent use of those remaining claims that serve to perpetuate the substance of the abandoned claims.

In light of RELEEV's existing market penetration and in light of its substantial profit margin, the court does not find that a preliminary injunction will destroy Ms. Squires's life work.

Whatever adverse effect it may have is a price that must be paid for failing to take curative action voluntarily for such a long period of time.

D. Public Interest: There is an obvious public interest in preventing misleading advertisements, an interest that "is particularly strong where over-the-counter drugs are concerned." Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., 290 F.3d 578, 597 (3d Cir. 2002). That interest is served by the issuance of a preliminary injunction in this case.

There is also a public interest in encouraging the creation of new and useful products and the furthering of competition. Merix's RELEEV will still be able to compete in the cold sore market. It will be given a reasonable period of time to remove from its newest packaging the remaining claims that suggest falsely that RELEEV cures colds sores. That is, it must remove the statement "1 Day Cold Sore Treatment" and it must remove the "Before" and "After" photographs. The court has rejected Glaxo's demand that Merix refrain from claiming that RELEEV provides relief of symptoms within 24-hours.

The issuance of a preliminary injunction serves the public interest.

VI. Conclusion

Glaxo has established that, applying the applicable criteria, it is entitled to the issuance of a preliminary injunction. The court will issue an appropriate injunction order. Glaxo shall post a bond of $500,000.

Dated: September 13, 2005

/S/ Dickinson R. Debevoise
DICKINSON R. DEBEVOISE
U.S.S.D.J.